

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/829,511 Confirmation No.: 7340
Applicant : SUNDAR, Rangarajan
Filed : April 22, 2004
TC/A.U. : 3734
Examiner : DOWE, Katherine

Docket No. : P1070
Customer No. : 28390
Title : **STENT WITH IMPROVED SURFACE ADHESION**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF RANGARAJAN SUNDAR & PEIWEN CHENG
UNDER 37 C.F.R. 1.131 and 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We acknowledge that willful false statements and the like are punishable by fine or imprisonment or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. All statements contained herein made of our own knowledge are true and all statements made on information and belief are believed to be true.

1. We, RANGARAJAN SUNDAR & PEIWEN CHENG, are former employees of Medtronic Vascular, Inc., where we worked and performed research relating to the above named application since prior to February 15, 2002.

2. We are the inventors named in, and are the inventors of the subject matter sought to be patented under, United States Patent Application Serial No. 10/829,511, filed April 22, 2004, which claims priority to United States Provisional Patent Application No. 60/464,440, filed April 22, 2003.

3. The attached Exhibit A is a copy of documents illustrating a date of conception of the present invention prior to at least February 15, 2002.

4. Prior to the filing date of the provisional patent application, we worked diligently with patent attorneys to prepare for the filing of a provisional patent application that was filed with the USPTO on April 22, 2003, and subsequently assigned Application Serial No. 60/464,440.

5. The above paragraphs illustrate prior conception and reasonable due diligence during at least the time between February 15, 2002, and the April 22, 2003, filing date of Application Serial No. 60/464,440.

Rangarajan Sundar

RANGARAJAN SUNDAR (signed)

7/22/2009

Date

RANGARAJAN SUNDAR

RANGARAJAN SUNDAR (print)

PEIWEN CHENG (signed)

Date

PEIWEN CHENG (print)

3. The attached Exhibit A is a copy of documents illustrating a date of conception of the present invention prior to at least February 15, 2002.

4. Prior to the filing date of the provisional patent application, we worked diligently with patent attorneys to prepare for the filing of a provisional patent application that was filed with the USPTO on April 22, 2003, and subsequently assigned Application Serial No. 60/464,440.

5. The above paragraphs illustrate prior conception and reasonable due diligence during at least the time between February 15, 2002, and the April 22, 2003, filing date of Application Serial No. 60/464,440.

RANGARAJAN SUNDAR (signed)

Date

RANGARAJAN SUNDAR (print)

Peiwen Cheng
PEIWEN CHENG (signed)

July 17, 2009
Date

PEIWEN CHENG
PEIWEN CHENG (print)

Exhibit A

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5/22/01

Objective: To coat a monolayer of amino-silane as organic layer on stent to function as a primer prior to polymer coating. This experiment was conducted by Peiwén Cheng and Ro Sunda.

Preparation of Amino Silane

0.5 mL Amino Silane T2910 (5% solution)
9.0 mL Methanol, HPLC grade
0.5 mL Water (De-ionized, sterile)
10.0 mL Total

Amino Silane Vendor: United Chemical Technology
Chemical Name: Trimethoxy-Silylpropyl diethylene triamine
T2910 Catalog Item. STENTS were immersed for 1 minute in Amino Silane before coating with PCL.

Preparation of 1% PCL Solution

Weight of PCL = 1.0043 grams

Volume of THF = 99.0 mL

Total ~ 100 mL

Lot number of PCL = D99142

P Cleaning of Stents (Total 10 stents)

Re. 1ST IPA Sonication = 5 minutes

Re. Re. Meine 1ST 2nd ~~IPA~~ Sonication = 5 minutes

2nd IPA Sonication = 5 minutes

1st DI Water Wash

2nd DI Water Wash

NaOH (1N) Sonication = 5 minutes

DI Water Sonication = 5 minutes

DI Water Sonication = 5 minutes

DI Water Sonication = 5 minutes

Nitrogen Dry (lost 4 stents during N₂ blow off)

Heated in oven (no vacuum) = 15 minutes @ 50°C

Ro Sunda

5/22/01

5/22/01 Coating of mono layer amino silane as primer

Stents were removed from oven after 15 minutes and immersed in 1% PEG solution for 10 seconds and placed on Corrosel rack for drying. Thus three stents had amino silane treatment (experiment) while the remaining three were control and had no treatment. The Corrosel rack was placed in an oven (no vacuum) at 30°C for ~1.5 hours. They were looked for about 5 minutes and inspected under a microscope.

Microscope observations

It appears that the amino silane coated stents had more wetting of the polymer (PCL) there were less bare metal visible hence more coating coverage. The control appeared to be less wettable.

Coating observations

The 5% solution of amino silane is probably too much for imparting a mono layer. After coating the stent and curing it for 15 minutes we noticed (Peiwen Cheng & R. Sundar) that there was white powdery material adhered to stents.

Hence concentration of amino silane solution should be targeted for 1% or less, to

These experiments are designated as follows:

8-1118-1
-2 } control
-3 }

8-1118-4 } with Amino silane T-2910
-5 }
-6 }

Samples 8-1118-1 & 8-1118-6 to be submitted to Sembra.

R. Sundar

5/22/01

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5/25/01

Coating a monolayer of Amino Silane as primer

SEM observations

SEM observations via several photos show that the amino silane treated stents had less metal exposure or more wetting. However this could be misleading since the stents were not subjected to uniform dipping by hand. There is some indication that wettability with the use of amino silane is somewhat better but more tests need to be conducted before drawing conclusions.

front standard
5/25/01

R. Sundar
5/25/01

